

## **EU DECLARATION OF CONFORMITY**

**Document No. :** DOC-005-01

**Rev:** A1

**Manufacturer:** Orantech Inc.

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New District, Shenzhen, China.518106

**EC- Representative:** Cables and Sensors B.V.

Zekeringstraat 21B  
1014 BM Amsterdam, Netherlands

**Product Name :** NIBP Cuff

**Product Models:** Please see the Annex I

**UMDNS Code :** 11073

**Classification :** Class I, Rule 1 (According to Annex IX of directive 93/42/EEC)


**Conformity Assessment Route :** Annex VII of directive the 93/42/EEC

We, Orantech Inc., herewith declare under our sole responsibility that the stated medical devices meet the transposition into national law, the provisions of council directive 93/42/EEC of 14 June, 1993 concerning medical devices; including, on March 21, 2010, the amendments by council directive 2007/47/EEC. All supporting documents are retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for doc.

**Standard Applied :**

EN ISO 14971:2012	EN ISO 15223-1:2016
EN 1041:2008	ISO 81060-1:2007
EN ISO 10993-1:2018	EN ISO 10993-5:2009
EN ISO 10993-10:2010	

**Notified Body :** TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany

**CE mark :** 

**Valid Date From :** 2018-07-10

**Valid Date Until :** 2022-09-03

**Place, Date of Issue :**

Shenzhen, July. 10, 2018

**Signature :** 

**Position:** General Manager

**Orantech Inc.**

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**Annex I List of NIBP Cuffs**

BP-10BS	BP-10BD	BP-10NS	BP-10ND
BP-20BS	BP-20BD	BP-20NS	BP-20ND
BP-30BS	BP-30BD	BP-30NS	BP-30ND
BP-40BS	BP-40BD	BP-40NS	BP-40ND
BP-50BS	BP-50BD	BP-50NS	BP-50ND
BP-60BS	BP-60BD	BP-60NS	BP-60ND
BP-70BS	BP-70BD	BP-70NS	BP-70ND
BP-80BS	BP-80BD	BP-80NS	BP-80ND
BP-90BS	BP-90BD	BP-90NS	BP-90ND
BPD-11WS	BPD-11WD		
BPD-12WS	BPD-12WD		
BPD-13WS	BPD-13WD		
BPD-14WS	BPD-14WD		
BPD-15WS	BPD-15WD		
BPD-20WS	BPD-20WD		
BPD-30WS	BPD-30WD		
BPD-40WS	BPD-40WD		
BPD-50WS	BPD-50WD		
BPD-60WS	BPD-60WD		
BPD-70WS	BPD-70WD		
BPD-80WS	BPD-80WD		
BPD-90WS	BPD-90WD		